K130604

PRISMATIK
DENTALCRAFT, INC.

005-510 (k) Summary-807.92(c)

This 510 (K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

SEP 12 2013

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite IJK, Irvine, CA 92612
Company Phone:	949-225-1269
Company FAX:	949-553-0924
Facility Registration Number:	3005477956
Primary Contact Person:	Armin Zehtabchi, (949) 225-1234 Senior RA/QA, 510(K) Project Manager
Secondary Contact Person	Marilyn Pourazar, (949) 225-1269 Senior Director, RA/QA
Date Summary Prepared:	June 21, 2013

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Universal Paste Stains and Glaze
21 CFR Reference:	21 CFR 872.6660
21 CFR Common Name:	Porcelain powder for clinical use
Classification:	Class II
Product Code:	EIH
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	3M's Bellus Shading Kit-K090718

D. **DEVICE DESCRIPTION**

Prismatik's Universal Paste Stains and Glaze are based on Silicate Sintered Glass Ceramic that is classified as Porcelain powder for clinical use (21 C.F.R. § 872.6660) and are available in a variety of colors. They include stain pastes, a glazing paste, and a liquid which can be used to thin the pastes. The pastes serve solely for the color staining and glazing of the surfaces of restorations.

The Universal Paste Stains and Glaze contains 17 stain shades, Fluorescent Paste Glaze, and Stain and Glaze Liquid, which are all silicate glass based.

The Stains are available in colors A, B, C, D and A Light, B Light, C Light, D Light, as well as White, Yellow, Orange, Brown, Dark Brown, Blue, Purple, Dark Pink, and Grey. The Fluorescent Paste Glaze is used to achieve an esthetic finishing coat. It also provides fluorescent properties under ultra-violet lighting. The Stain and Glaze Liquid can be mixed with the pastes in order to modify the consistency, and can also be used to clean the brush.

Work flow past production:

The work flow paste production includes melting, milling/sieving, shading and paste preparation, and the process flow is demonstrated below:

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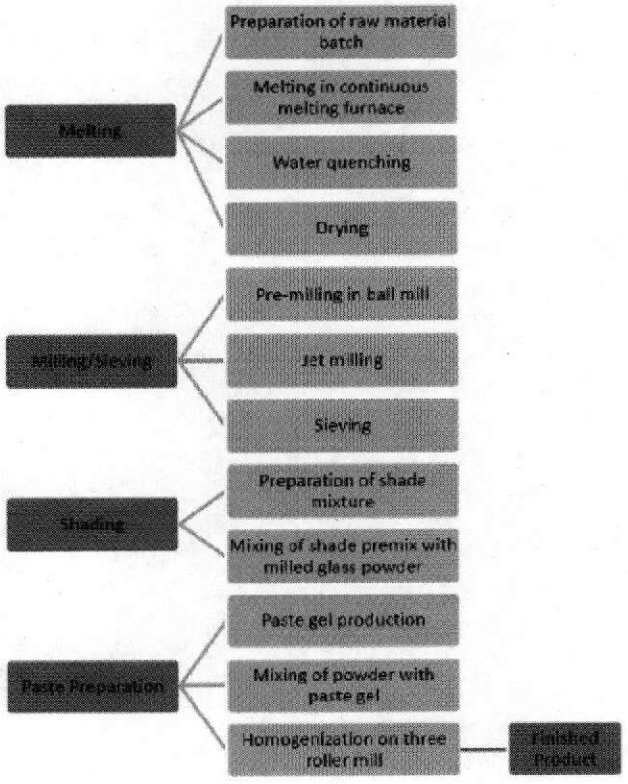
Work flow paste production, glaze/stains/shades ZT

1. Melting
2. Milling/Sieving
3. Shading
4. Paste preparation



estetic ceram ag
Austrasse 15 · Postfach 223 · 9495 Triesen · Liechtenstein · Telefon +423 237 48 58 · Fax +423 237 48 59 · info@esteticceram.com · www.esteticceram.com

E. INDICATIONS FOR USE

Prismatik's Universal Paste Stains and Glaze are intended to be used in dental applications for coloration and finishing of glass ceramic and zirconia-based restorations.

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE NEW DEVICE AND THE PREDICATE DEVICES

The following comparison table of the technological characteristics of the new device and the predicate devices outlines and provides the similarities and the substantial equivalency of the Prismatik's™ Universal Paste Stains and Glaze and the 3M's Bellus Shading Kit-K090718.

Comparison of the Technological Characteristics of the New Device and the Predicate Devices

Elements of Comparison	Prismatik™ Universal Paste Stains and Glaze	3M's Bellus Shading Kit-K090718
General Material	Powder, porcelain	Same
Indications	Prismatik's Universal Paste Stains and Glaze are intended to be used in dental applications for coloration and finishing of glass ceramic and zirconia-based restorations.	Color staining and glazing of glass ceramic restorations made from 3M ESPE's Glass Ceramics "Jolly."
Biocompatibility	Yes	Same
Sterility	Non-sterile	Same
Machining and Sintering	Yes	Same
Performance	Simulating the natural tooth dentine	Same

G. DETERMINITION OF SUBSTANTIAL EQUIVALENCE

The above comparison table of the technological characteristics of the new device and the predicate devices was provided for the substantial equivalency of the Prismatik's™ Universal Paste Stains and Glaze and the 3M's Bellus Shading Kit-K090718. Prismatik believes that the comparative data presented, demonstrate that Prismatik™ Universal Paste Stains and Glaze are essentially the same as currently marketed devices for the same indication for use, and supports our claim of substantial equivalence to predicate Class II devices under the classification of Porcelain powder for clinical use (21 CFR 872.6660) that have previously been found to be substantially equivalent. Both the new and the predicate device consist of general porcelain powder material (Product Code: EIH), that is biocompatible for the same indication for use.

H. SUMMARYOF NON-CLINICAL TESTING

Non-clinical test data was used to support the substantial equivalency. To provide evidence for safety, a biocompatibility testing was carried out. The raw materials were tested for cytotoxicity (acc. DEN EN ISO 10993-5) with negative result. From chemical point of view, the porcelains investigated were similar in composition and show similar solubility acc DIN EN ISO 6872.

I. CONCLUSION FROM THE NON-CLINICAL TESTING

The results of the above described studies demonstrate that Prismatik's Universal Paste Stains and Glaze is as safe and effective as the cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2013

Prismatik Dentalcraft, Inc.
C/O Mr. Armin Zehtabchi
Senior RA Specialist
2212 Dupont Drive, Suite IJK
Irvine, CA 92612

Re: K130604
Trade/Device Name: Universal Paste Stains and Glaze
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: June 26, 2013
Received: June 27, 2013

Dear Mr. Zehtabchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PRISMATIK
DENTALCRAFT, INC.

004-Indications for Use Statement

510 (K) Number (if known): K130604

Device Name: Universal Paste Stains and Glaze

Indications for Use: Prismatik's Universal Paste Stains and Glaze are intended to be used in dental applications for coloration and finishing of glass ceramic and zirconia-based restorations.

Prescription Use: Yes ☒ **No** ☐
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use: Yes ☐ **No** ☒
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K130604